Drug-Eluting Balloons

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Potential conflicts of interest

Speaker’s name: Klaus Bonaventura

☒ I have the following potential conflicts of interest to report:

☐ Grant/Research Support
☒ Consulting Fees/Honoraria: B. Braun, Boehringer, B. Braun, Bristol-Myers Squibb, Lilly, Medtronic, Pfizer, Sanofi Aventis
☐ Major Stock Shareholder/Equity
☐ Royalty Income
☒ Ownership/Founder: Personal MedSystems
☐ Intellectual Property Rights
☐ Other Financial Benefit
Interventional Cardiology - The 2\textsuperscript{nd} revolution

1977
1. Balloon (PTCA):
Andreas Gruntzig performs the first PTCA in Zurich, Switzerland

1988
2. Bare Metal Stent (BMS):
Julio Palmaz and Richard Schatz develop a stainless steel stent for coronary applications
Intimal dissection following balloon angioplasty
Bare Metal Stent
Dual Antiplatelet Therapy (DAPT) after Bare Metal Stent

⇒ 4 weeks
Restenosis after Bare Metal Stenting
Interventional Cardiology - The 3rd Revolution

1977
1. Balloon (PTCA): Andreas Gruntzig performs the first PTCA in Zurich, Switzerland

1988
2. Bare Metal Stent (BMS): Julio Palmaz and Richard Schatz develop a stainless steel stent for coronary applications

2002 - 2003
3. Drug-eluting stents (DES): introduced to the European and U.S. markets
Drug-Eluting Stent

Without Drug Coating

With Drug Coating
Dual Antiplatelet Therapy after Drug-Eluting Stent

(6-) 12 months
Drug-Eluting Stent

ISAR-DESIRE 2: TLR

Stent thrombosis:
SES 6.3% vs. PES 6.1% (p = 0.98)

$P = 0.52$

Byrne, R, TCT 2009
Heterogeneity of neointimal Healing after DES Placement

Joner M et al. J Am Coll Cardiol, 2008; 52:333-342
### ESC-Guidelines Atrial Fibrillation

<table>
<thead>
<tr>
<th>Haemorrhagic risk</th>
<th>Clinical setting</th>
<th>Stent implanted</th>
<th>Anticoagulation regimen</th>
</tr>
</thead>
</table>
| Low or intermediate (e.g. HAS-BLED score 0–2) | Elective | Bare-metal | 1 month: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day  
**Lifelong:** VKA (INR 2.0–3.0) alone |
| | Elective | Drug-eluting | 3 (–olimus* group) to 6 (paclitaxel) months: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day  
**Up to 12th month:** combination of VKA (INR 2.0–2.5) + clopidogrel 75 mg/day\(^b\)  
(or aspirin 100 mg/day)  
**Lifelong:** VKA (INR 2.0–3.0) alone |
| ACS              | Bare-metal/drug-eluting | 6 months: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day  
**Up to 12th month:** combination of VKA (INR 2.0–2.5) + clopidogrel 75 mg/day\(^b\)  
(or aspirin 100 mg/day)  
**Lifelong:** VKA (INR 2.0–3.0) alone |
| High (e.g. HAS-BLED score ≥3) | Elective | Bare-metal\(^c\) | 2–4 weeks: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day  
**Lifelong:** VKA (INR 2.0–3.0) alone |
| ACS              | Bare-metal\(^c\) | 4 weeks: triple therapy of VKA (INR 2.0–2.5) + aspirin ≤100 mg/day + clopidogrel 75 mg/day  
**Up to 12th month:** combination of VKA (INR 2.0–2.5) + clopidogrel 75 mg/day\(^b\)  
(or aspirin 100 mg/day)  
**Lifelong:** VKA (INR 2.0–3.0) alone |
Interventional Cardiology - The 4<sup>th</sup> Revolution

¬ Drug-Coated Balloon (DCB) = Drug-Eluting Balloon (DEB)
¬ Drug-Eluting Bioresorbable Vascular Scaffold (BVS) Stent
„Leaving Nothing Behind“
DCB & BVS
Drug-Coated Balloon (DCB)

The New England Journal of Medicine

ORIGINAL ARTICLE

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

Bruno Scheller, M.D., Christoph Hehrlein, M.D., Wolfgang Bocksch, M.D., Wolfgang Rutsch, M.D., Dariush Haghi, M.D., Ulrich Dietz, M.D., Michael Böhm, M.D., and Ulrich Speck, Ph.D.

ABSTRACT

BACKGROUND
Treatment of coronary in-stent restenosis is hampered by a high incidence of recurrent in-stent restenosis. We assessed the efficacy and safety of a paclitaxel-coated balloon in this setting.

METHODS
We enrolled 52 patients with in-stent restenosis in a randomized, double-blind, multicenter trial to compare the effects of a balloon catheter coated with paclitaxel (3 µg per square millimeter of balloon surface area) with those of an uncoated balloon catheter in coronary angioplasty. The primary end point was late luminal loss as seen on angiography. Secondary end points included the rates of restenosis (a binary variable) and major adverse cardiac events.

From Universitätsklinikum des Saarlandes, Homburg/Saar (B.S., M.B.); Universitätsklinikum, Freiburg (C.H.); Campus Virchow-Klinikum (W.B.) and Campus Charité Mitte (W.R., U.S.), Universitätsklinikum Charité, Berlin; Universitätsklinikum Mannheim, Ruprecht Karls Universität Heidelberg, Mannheim (D.H.); and Deutsche Klinik für Diagnostik, Wiesbaden (U.D.)—all in Germany. Address reprint requests to Dr. Scheller at the Klinik für Innere Medizin III, Universitätsklinikum des Saarlandes, Homburg/Saar, Germany, or at bruno.scheller@uniklinikum-saarland.de.

Drug-Coated Balloon (DCB)
Drug-Coated Balloon (DCB)

Drug-Eluting Stent
- Slow release
- Persistent drug exposure
- ~ 100 - 200 µg dose
- Polymer
- Stent mandatory

Drug-Coated Balloon
- Immediate release
- Short-lasting exposure
- ~ 300 - 600 µg dose
- No polymers
Drug-Coated Balloon

- In-Stent Restenosis
- Small Vessel Disease
- Bifurcation Lesions
- De-Novo Coronary Lesions
Recommendations by the German Consensus Group

Treatment of In-stent Restenosis (ISR)
- **Pre-dilation**
  - Focal
  - Diffuse
- **Treatment**
  - Overlap only the pre-dilated area by 2 - 3 mm
  - Overlap stent by 2 - 3 mm
  - Lesions < 30 mm → 2xSpiral Please (DEB) overlapping by 3 - 5 mm
- Dissection
  - Yes
  - No
- **DAPT**
  - BMS ISR 4 weeks
  - DES ISR 4 weeks + remaining life (or 12 months)

Treatment of Small Vessel Disease (SVD)
- Successful pre-dilation = Residual stenosis < 30%, no flow-limiting dissection
- **Treatment**
  - Yes
  - Sequent Please (DEB)
  - BMS spot stenting followed by Sequent Please (DEB)
  - DES/BMS
- No
  - 4 weeks
  - 6 - 12 months
  - 12 months/4 weeks

Treatment of Bifurcation Stenoses
- Successful pre-dilation in the SB and MB 0.8 - 1.0
- **Treatment**
  - Yes = No dissection in MB
  - Sequent Please (DEB) MB 0.8 - 1.0
  - Sequent Please (DEB) MB 0.8 - 1.0
- No = Dissection in MB
  - Sequent Please (DEB) SB 0.8 - 1.0
  - BMS MB
- **DAPT**
  - 4 weeks
  - 12 months
  - 12 months
Drug-Coated Balloon

- In-Stent Restenosis
- Small Vessel Disease
- Bifurcation Lesions
- De-Novo Coronary Lesions
Efficacy and Safety of Paclitaxel-Coated Balloons in Coronary In-Stent Restenosis

Two trials
- separately randomized
- double-blind, multicenter
- identical protocol
- 108 patients in total

Paccocath ISR I: 52 patients

Paccocath ISR II: 56 patients
### Table 2. (Continued.)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Uncoated Balloon (N=26)</th>
<th>Paclitaxel-Coated Balloon (N=26)</th>
<th>Absolute Difference (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Angiographic findings at 6 mo</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of patients</td>
<td>23</td>
<td>22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimal luminal diameter — mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent</td>
<td>1.60±0.89</td>
<td>2.31±0.66</td>
<td>-0.71 (-1.18 to 0.24)</td>
<td>0.004</td>
</tr>
<tr>
<td>In-segment</td>
<td>1.57±0.86</td>
<td>2.22±0.57</td>
<td>-0.65 (-1.09 to 0.21)</td>
<td>0.005</td>
</tr>
<tr>
<td>Late luminal loss — mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent</td>
<td>0.76±0.86</td>
<td>0.09±0.49</td>
<td>0.67 (0.24 to 1.09)</td>
<td>0.003</td>
</tr>
<tr>
<td>In-segment</td>
<td>0.74±0.86</td>
<td>0.03±0.48</td>
<td>0.70 (0.28 to 1.12)</td>
<td>0.002</td>
</tr>
<tr>
<td>Restenosis — no. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent</td>
<td>10 (43)</td>
<td>1 (5)</td>
<td>0.39 (0.15 to 0.63)</td>
<td>0.002</td>
</tr>
<tr>
<td>In-segment</td>
<td>10 (43)</td>
<td>1 (5)</td>
<td>0.39 (0.15 to 0.63)</td>
<td>0.002</td>
</tr>
</tbody>
</table>
PACCOCATH ISR I + II: Long-term
Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

<table>
<thead>
<tr>
<th></th>
<th>Uncoated Balloon</th>
<th>Drug Coated Balloon</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>54</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>5.2 ± 1.5 yrs</td>
<td>5.6 ± 0.9 yrs</td>
<td>0.108</td>
</tr>
<tr>
<td>Death</td>
<td>8 (14.8 %)</td>
<td>5 (9.3 %)</td>
<td>0.556</td>
</tr>
<tr>
<td>MI</td>
<td>8 (14.8 %)</td>
<td>5 (9.3 %)</td>
<td>0.556</td>
</tr>
<tr>
<td><strong>TLR</strong></td>
<td><strong>21 (38.9 %)</strong></td>
<td><strong>5 (9.3 %)</strong></td>
<td><strong>0.001</strong></td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>0</td>
<td>0</td>
<td>1.000</td>
</tr>
<tr>
<td>Stroke</td>
<td>5 (9.3 %)</td>
<td>5 (9.3 %)</td>
<td>1.000</td>
</tr>
<tr>
<td><strong>MACE</strong></td>
<td><strong>32 (59.3 %)</strong></td>
<td><strong>15 (27.8 %)</strong></td>
<td><strong>0.002</strong></td>
</tr>
</tbody>
</table>

Scheller, PCR 2011
### PEPCAD II
Paclitaxel-Coated Balloon Catheter Versus Paclitaxel-Coated Stent for the Treatment of Coronary In-Stent Restenosis

<table>
<thead>
<tr>
<th></th>
<th>Drug-Coated Balloon</th>
<th>Drug-Eruting Stent</th>
<th>Difference (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiographic follow-up, n (%)</td>
<td>57 (86.4)</td>
<td>59 (90.8)</td>
<td>-0.04 (-0.15 to 0.05)</td>
<td>0.43</td>
</tr>
<tr>
<td>Minimal lumen diameter</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent, mm</td>
<td>2.08±0.56</td>
<td>2.11±0.78</td>
<td>-0.04 (-0.29 to 0.21)</td>
<td>0.77</td>
</tr>
<tr>
<td>In-segment, mm</td>
<td>2.03±0.56</td>
<td>1.96±0.82</td>
<td>0.07 (-0.19 to 0.33)</td>
<td>0.60</td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>29.4±17.5</td>
<td>34.2±24.3</td>
<td>-4.7 (-12.5 to 3.1)</td>
<td>0.23</td>
</tr>
<tr>
<td>Late lumen loss, mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent</td>
<td>0.19±0.39</td>
<td>0.45±0.68</td>
<td>-0.26 (-0.47 to -0.06)</td>
<td>0.01</td>
</tr>
<tr>
<td>In-segment</td>
<td>0.17±0.42</td>
<td>0.38±0.61</td>
<td>-0.21 (-0.40 to -0.02)</td>
<td>0.03</td>
</tr>
<tr>
<td>Late lumen loss index, mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent</td>
<td>0.12±0.26</td>
<td>0.28±0.48</td>
<td>-0.16 (-0.30 to -0.02)</td>
<td>0.03</td>
</tr>
<tr>
<td>In-segment</td>
<td>0.11±0.29</td>
<td>0.30±0.53</td>
<td>-0.19 (-0.35 to -0.03)</td>
<td>0.02</td>
</tr>
<tr>
<td>Binary restenosis rate, n (%)</td>
<td>4 (7)</td>
<td>10 (16.9)</td>
<td>-0.10 (-0.23 to 0.03)</td>
<td>0.17</td>
</tr>
<tr>
<td></td>
<td>4 (7)</td>
<td>12 (20.3)</td>
<td>-0.13 (-0.27 to 0.01)</td>
<td>0.06</td>
</tr>
</tbody>
</table>
Follow-up rate: 94% (47/50 Lesions, PEB group: 23, BA group: 24)

<table>
<thead>
<tr>
<th></th>
<th>Paclitaxel-Eluting Balloon</th>
<th>Conventional Balloon Angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late luminal loss (in-lesion)</td>
<td>0.17 ± 0.45</td>
<td>0.72 ± 0.56</td>
</tr>
<tr>
<td>Late luminal loss (in-segment)</td>
<td>0.18 ± 0.45</td>
<td>0.72 ± 0.55</td>
</tr>
<tr>
<td>Binary restenosis</td>
<td>2 (8.7)</td>
<td>15 (62.5)</td>
</tr>
<tr>
<td>Target lesion revascularization</td>
<td>1 (4.3)</td>
<td>10 (41.7)</td>
</tr>
</tbody>
</table>
Cost Effectiveness of Paclitaxel-Eluting Balloon Catheter in Patients with Bare-Metal Stent Restenosis

Clin Res Cardiol
DOI 10.1007/s00392-012-0428-2

Cost-effectiveness of paclitaxel-coated balloon angioplasty and paclitaxel-eluting stent implantation for treatment of coronary in-stent restenosis in patients with stable coronary artery disease

Klaus Bonaventura · Alexander W. Leber · Christian Sohns · Mattias Roser · Leif-Hendrik Boldt · Franz X. Kleber · Wilhelm Haverkamp · Marc Dorenkamp

Received: 12 December 2011/Accepted: 8 February 2012
© Springer-Verlag 2012
Initial procedure costs:
- DCB: € 3,604.14
- DES implantation: € 3,309.66

Over a 12-month time horizon:
- DCB strategy: € 4,130.38
- DES implantation: € 5,305.30

DCB slightly more effective in terms of life expectancy than the DES strategy (0.983 versus 0.976 years).

Δ € 294.48
Δ € 1,174.92
| Drug-eluting balloons should be considered for the treatment of in-stent restenosis after prior BMS. | IIa | B |
| Tornus catheter may be used for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting. | IIb | C |
| Cutting or scoring balloons may be considered for dilation of in-stent restenosis, to avoid slipping-induced vessel trauma of adjacent segments. | IIb | C |
| IVUS-guided stent implantation may be considered for unprotected left main PCI. | IIb | C |
| Mesh-based protection may be considered for PCI of highly thrombotic or SVG lesions. | IIb | C |
| For PCI of unstable lesions, intracoronary nitroprusside or other vasodilators may be considered for pharmacological treatment of no-reflow. | IIb | C |
DEB only

- Male, 55 years
- PCI of In-stent Restenosis of RCA
In-stent Restenosis of RCA
RCA with guidewire
Predilatation with 3.5/15 mm balloon
RCA after predilatation
RCA with DCB 3.5/20 mm (Sequent Please)
RCA with DCB 3.5/17 mm (Sequent Please)
RCA, final result after DCB only
RCA, 4 months after DCB only
Drugs-Coated Balloon

- In-Stent Restenosis
- Small Vessel Disease
- Bifurcation Lesions
- De-Novo Coronary Lesions
PEPCAD I
Treatment of small coronary arteries with a paclitaxel-coated balloon catheter

→ Prospective, single-arm, observational, multi-center
→ 118 patients, angiographic follow-up 89%
→ Paclitaxel eluting balloon Sequent Please in patients with lesions in coronary arteries of 2.25 – 2.8 mm in diameter.
→ Endpoint: late lumen loss at 6 months.
**PEPCAD I**

Treatment of small coronary arteries with a paclitaxel-coated balloon catheter

- **DEB only: 6 Months Results**

<table>
<thead>
<tr>
<th>Follow-up angiography (82 Patients)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Late lumen loss In-segment</td>
<td>$0.16 \pm 0.38$ mm</td>
</tr>
<tr>
<td>Binary restenosis rate In-segment</td>
<td>4 (5.5 %)</td>
</tr>
<tr>
<td>Target lesion revascularization</td>
<td>4 (4.9 %)</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
</tr>
</tbody>
</table>
PEPCAD I
Treatment of small coronary arteries with a paclitaxel-coated balloon catheter

DEB only: 1-Year MACE Results

<table>
<thead>
<tr>
<th></th>
<th>DEB ITT</th>
<th>DEB Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>114</td>
<td>82</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>1.7%</td>
<td>0%</td>
</tr>
<tr>
<td>TLR</td>
<td>11.9%</td>
<td>4.9%</td>
</tr>
<tr>
<td>Death</td>
<td>2.9%</td>
<td>0%</td>
</tr>
<tr>
<td>MI</td>
<td>1.7%</td>
<td>1.3%</td>
</tr>
<tr>
<td>MACE</td>
<td>15.3%</td>
<td>6.1%</td>
</tr>
</tbody>
</table>
Paclitaxel-coated balloon DIOR® vs. Taxus DES in small coronary vessels (≤ 2.75 mm), n=28 + 29 patients

Cortese B et al. Heart 2010;96:1291-1296
Roughened Balloon Surface vs. Matrix Coating

Matrix Coating - Paclitaxel Iopromide
Sequent Please

Cremers B et al., Clin Res Cardiol 2009; 98: 325–330
Drug-Coated Balloon

- In-Stent Restenosis
- Small Vessel Disease
- Bifurcation Lesions
- De-Novo Coronary Lesions
Consensus Statement of the German consensus group: SeQuent® Please - DEB only: Treatment of Bifurcation Stenoses

Successful pre-dilation in the SB and MB 0.8 – 1.0

Yes = No dissection in MB

Sequent Please (DEB) SB 0.8 – 1.0

Sequent Please (DEB) MB 0.8 – 1.0

4 weeks

No = Dissection in MB

Sequent Please (DEB) SB 0.8 – 1.0

BMS MB

Sequent Please (DEB) MB 0.8 – 1.0

SB < 75% + TIMI 3

No SB dilation, no kissing balloon

12 months

SB > 75% or TIMI < 3

Kissing balloon with conventional balloon

12 months

DAPT
The procedure was successful in all patients.

Additional stenting of the main branch was needed in 3 (7.9%) interventions.

Bonaventura K, Asia PCR 2013
DCB in Bifurcation Lesions: Potsdam Registry

- No MACE (cardiac death, myocardial infarction, target lesion revascularization) occurred up to 30 days.
- Target lesion revascularization at 12 months: 0%
- Duration of DAPT was 4.2 ± 3.8 months.
Drug-Coated Balloon

- In-Stent Restenosis
- Small Vessel Disease
- Bifurcation Lesions
- De-Novo Coronary Lesions
Two Different Causes for Restenosis

Recoil & Negative Remodeling

**Stenting (BMS, DES)**

*Drug-Eluting Bioresorbable Vascular Scaffold (BVS) Stent*
Two Different Causes for Restenosis

Recoil & Negative Remodeling

Neointimal Hyperplasia

Stenting (BMS, DES)

Drug-Eluting Bioresorbable Vascular Scaffold (BVS) Stent

Drug-Coated Balloon

(Drug-Eluting Bioresorbable Vascular Scaffold (BVS) Stent)
## Late lumen loss after DCB in De-novo Lesions

<table>
<thead>
<tr>
<th>Trial</th>
<th>Number of patients</th>
<th>Intervention</th>
<th>Indication</th>
<th>Late lumen loss</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEPCAD I SVD ¹</td>
<td>(n=118)</td>
<td>SeQuent™ Please (n=82) vs. SeQuent™ Please + BMS</td>
<td>De novo, small vessels</td>
<td>0.16 mm</td>
<td>6 months</td>
</tr>
<tr>
<td>PEPCAD V²</td>
<td>(n=28)</td>
<td>SeQuent™ Please</td>
<td>De novo, bifurcation (side branch)</td>
<td>0.21 mm</td>
<td>6 months</td>
</tr>
<tr>
<td>PICCOLETO³</td>
<td>(n=60)</td>
<td>Dior™ II (n=29) vs. DES</td>
<td>De novo, small vessels</td>
<td>Not published</td>
<td>6 months</td>
</tr>
<tr>
<td>DEBUIT⁴</td>
<td>(n=117)</td>
<td>Dior™ (n=40) vs. Dior™ + BMS vs. DES</td>
<td>De novo, bifurcation</td>
<td>0.11 mm</td>
<td>9 months</td>
</tr>
<tr>
<td>Valentines II⁵</td>
<td></td>
<td>Dior™ II</td>
<td>De novo</td>
<td>0.30 (overall)</td>
<td>6-9 months</td>
</tr>
</tbody>
</table>

SeQuent Please World Wide Registry
PCB Treatment for De Novo Lesions: Clinical Events

<table>
<thead>
<tr>
<th>Trial Number of patients</th>
<th>Intervention</th>
<th>Indication</th>
<th>Duration of DAPT</th>
<th>Acute and late thrombosis at follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEPCAD I SVD(^1) (n=118)</td>
<td>SeQuent™ Please (n=82) vs. SeQuent™ Please + BMS</td>
<td>De novo, small vessels</td>
<td>1 month</td>
<td>DCB: 0%, DCB + BMS: 6.3%</td>
</tr>
<tr>
<td>PEPCAD V(^2) (n=28)</td>
<td>SeQuent™ Please</td>
<td>De novo, bifurcation (side branch)</td>
<td>3 months</td>
<td>DCB: 0%</td>
</tr>
<tr>
<td>PICCOLETO(^3) (n=60)</td>
<td>Dior™ II (n=29) vs. DES</td>
<td>De novo, small vessels</td>
<td>1 month in cases of stable angina and lone DEB use, 3 months in cases of DEB and provisional stent implantation</td>
<td>DCB: 0%, DES: 0%</td>
</tr>
<tr>
<td>DEBUIT(^4) (n=117)</td>
<td>Dior™ (n=40) vs. Dior™ + BMS vs. DES</td>
<td>De novo, bifurcation</td>
<td>DEB: 3 months, DEB + BMS: 3 months, DES: 12 months</td>
<td>DCB: 0% DCB + BMS: 0%, DES: 2.5%</td>
</tr>
<tr>
<td>Potsdam Heart Center (n=85)(^5)</td>
<td>SeQuent™ Please</td>
<td>De novo</td>
<td>5.4 months</td>
<td>DCB: 0%</td>
</tr>
</tbody>
</table>

Pre-dilation with conventional balloon, balloon/vessel ratio of 0.8-1.0
(cutting balloon, scoring balloon, high pressure balloon to provide a complete expansion)

- acceptable as final result
- major dissection (Type C-F), residual stenosis ≥ 30%, TIMI flow < III
„DEB-only“ Strategy

Pre-dilation with conventional balloon, balloon/vessel ratio of 0.8-1.0
(cutting balloon, scoring balloon, high pressure balloon to provide a complete expansion)

acceptable as final result

major dissection (Type C-F), residual stenosis ≥ 30%, TIMI flow < III

DES or BMS spot stenting followed by DCB avoiding geographic mismatch
Pre-dilation with conventional balloon, balloon/vessel ratio of 0.8-1.0

- Acceptable as final result
- "DEB only" strategy
  - Should extend the predilated area by 2-3 mm
  - Balloon/vessel ratio 0.8-1.0
  - 8-10 atm, 30 sec.

- Major dissection (Type C-F), residual stenosis $\geq 30\%$, TIMI flow $< III$

- DES
The acute results after DCB only intervention might show haziness, however there is a tendency on improvement with time.
Dual Antiplatelet Therapy after Drug-Coated Balloon

⇒ 4 weeks
DAPT and Triple Therapy as short as possible

- Planned surgery
- Bleeding event
- Increased bleeding risk
- Need for oral anticoagulation / triple therapy
  - Atrial fibrillation
  - Mechanical heart valve
  - Embolism
  - Thrombophilia
  ...
- Stentthrombosis
Drug-Coated Balloon (DCB)

DCB only

- Female, 67 years
- Elective intervention of M1CX, positive stress test
RH, M1CX before 2.5/15 mm balloon
RH, M1CX after 2.5/15 mm balloon
RH, M1CX with DCB 2.5/20 mm (Sequent Please)
RH, M1CX, “final result” after DCB only
RH, M1CX, 4 months after DCB only
Conclusions

- The use of DCB in in-stent restenosis, bifurcation lesions and small vessel disease is established.
- Favorable results in de-novo coronary artery disease
- No class-effect of DCB
- DEB only is not associated with a higher rate of acute or late thrombosis.
- Localized haziness after DCB angioplasty in de-novo lesions does not increase the risk of acute coronary thrombosis.
Conclusions

- The possible **reduction in the duration of DAPT** to one month may represent additional advantages regarding safety, patient compliance and costs for the “DCB only” strategy.

- **Short period of triple therapy** - especially in patients with atrial fibrillation and in patients with increased bleeding risk